DOCUMENT RESUME

ED 415 468 CG 028 245

AUTHOR Gillespie, Janet F.

TITLE Institutional Review Boards and University Student Research: Learning Opportunities.

PUB DATE 1997-08-16

NOTE 12p.; Paper presented at the Annual Meeting of the American Psychological Association (105th, Chicago, IL, August 15-19, 1997).

PUB TYPE Information Analyses (070) -- Speeches/Meeting Papers (150)

EDRS PRICE MF01/PC01 Plus Postage.

DESCRIPTORS College Students; *Financial Support; *Higher Education; *Proposal Writing; *Research Opportunities; Research Proposals; Science Education; *Scientific Research; *Student Research

IDENTIFIERS *Institutional Review Boards; Science Majors

ABSTRACT

The process of getting one's research approved by an Institutional Review Board (IRB) is detailed in this paper. The article discusses the typical information expected in an IRB proposal and it describes an IRB's role in evaluating a proposed research project, including ethical and scientific questions. The paper focuses on the advantages that accrue to students who take the time to learn about IRBs early in their scientific careers; it also discusses pitfalls that beginning researchers must avoid when proposing research that may involve deception, remuneration of subjects, or sensitive topics. It is explained that most research universities have an IRB, whereas small colleges or undergraduate institutions may not have such a review board. The text opens with a brief history of IRBs, and the role that IRB's play in evaluating a proposed research project as ethical and scientific. Next, the process and steps involved in obtaining IRB approvals are detailed. Some caveats to consider when negotiating the IRB process are covered, as are the advantages that undergraduate students can reap from learning about IRBs. (RJM)

****
* Reproductions supplied by EDRS are the best that can be made *
* from the original document. *
****

ED 415 468

Institutional Review Boards and University Student Research: Learning Opportunities

Janet F. Gillespie

SUNY College at Brockport

PERMISSION TO REPRODUCE THIS MATERIAL HAS BEEN GRANTED BY

J. Gillespie

TO THE EDUCATIONAL RESOURCES INFORMATION CENTER (ERIC)

U.S. DEPARTMENT OF EDUCATION
Office of Educational Research and Improvement
EDUCATIONAL RESOURCES INFORMATION CENTER (ERIC)

☐ This document has been reproduced as received from the person or organization originating it.

☐ Minor changes have been made to improve reproduction quality.

• Points of view or opinions stated in this document do not necessarily represent official OERI position or policy.

Paper in: S.C. Tentoni & T. Kuther (Chairs), The research process: Getting started, finding topics, and ethics. Symposium presented at the 105th Annual Meeting of the American Psychological Association, Chicago, Illinois, August 16, 1997.

BEST COPY AVAILABLE

CG028245

Institutional Review Boards and University Student Research: Learning Opportunities

Introduction

It has been noted by writers in the area of research and ethics (e.g. Rosnow, Rotheram-Borus, Ceci, Blanck, & Koocher, 1993) that psychologists have, over the last 20 years, faced ever-greater demands for accountability in the ways in which they conduct research. While that may or may not have had a practical impact on the research training given students, it is true that in the 1990's, guidelines for conducting research are more explicit. These guidelines come from the federal government's Office for Protection from Research Risk (OPRR), a division of the Department of Health and Human Services. OPRR mandates are implemented and enforced at the university level by committees that are called Institutional Review Boards, or IRBs. Most U.S. campuses have an IRB, but in case there are any students sitting in the audience who are not familiar with the term, please don't feel uninformed. IRBs are also referred to as review committees for human participant research; ethics boards; or sometimes simply, "the human subjects committee". If you are in a graduate program at a research university, there is undoubtedly an IRB at your school. In contrast, some small colleges, or schools that are primarily undergraduate institutions, may not have an IRB. Similarly, community colleges, whose mission is more teaching than research, will typically not have an IRB either. However, if you are at a school that has an IRB, you should know that all research that involves human participants must go through IRB review before any data can be collected. No matter what the project, or the research question being asked, you should have IRB approval. Obviously, then, this pertains to faculty research, master's theses, and doctoral dissertations. It also applies to "senior" theses, undergraduate honors projects, term projects for classes, even class opinion

surveys in which one gathers information from one's peers and classmates about any topic. It applies to professors' handing out personality measures in class and having their students fill them out and learn to score the measures by analyzing their own responses. It applies to recruiting your roommate's friends for intellectual testing so you can practice administration of the WAIS-III for your assessment class. In summary, the domain of governance of campus IRBs is quite broad.

My background with IRBs did not extend beyond submitting proposals for approval until 1990, when I was invited to become a member of the IRB at my college, SUNY Brockport, in upstate New York. Since then I have reviewed dozens, if not hundreds, of proposals, attended many meetings of our IRB, and worked closely with the IRB chairperson. I will be covering four areas in this presentation. First, I will give a brief history of IRBs, and information on an IRB's role in evaluating a proposed research project as ethical and scientific. Second, I will describe the process and steps involved in obtaining IRB approval for one's research project. Third, I will point our some caveats and issues to note with caution while negotiating the IRB process for approval of one's project. Lastly, I will mention some of the advantages to undergraduate students of learning about IRBs.

History and Roles of Institutional Review Boards at U.S. Universities

Institutional Review Boards have been in existence in the United States since 1966. They began as a requirement for those seeking Public Health Service (PHS) grants from the federal government. Today there are an estimated 3,000 or more IRBs nationwide and over 500 in other countries. The beginnings of governmental concern over involvement of humans in research arose over 50 years ago following the abuse of large numbers of people in biomedical research

during World War II. The **Nuremberg Code** was drafted during war crimes trials for judgment of physicians who initiated invasive experiments on inhabitants of Nazi concentration camps. The basic elements of this code have remained the prototype for ethical standards of research that we follow today. Although we have had these standards since the late 1940's, even in our own country there have been examples of abuses since that time. For instance, the Tusekegee Syphilis Experiments (Jones, 1993), in which patients were not told of their diagnosis and not treated in order to study the course of the disease; and the injecting of patients with plutonium in northeastern U.S. hospitals without their knowledge, supposedly to study radiation effects ("Patients' names", 1993). In the area of psychological research, it's unlikely that the Milgram "obedience to authority" experiment (1974) would ever have received IRB approval today.

The principle of paramount importance in ethics codes is that **voluntary, informed consent** of participants is essential before they can be involved in research. Lacking consent, any kind of intrusive research is unethical, whether the individuals are exposed to harm or not. Some of the basic ethical principles which underly IRB guidelines include: **respect for persons and their capabilities**, including the idea that those with diminished autonomy, such as minors, are entitled to protection; **beneficience**, or that it is understood that the investigator will not harm the research participant physically or psychologically, will minimize risk of harm and maximize possible benefits; and **justice**, or the idea that individuals should be treated equally and fairly given the research question; that those who are confined, such as the institutionalized, shall not be single out because of easy availability. Accordingly, in evaluating a proposal as safeguarding the rights of human participants, an IRB will make a judgment regarding your project's plan for **informed consent, specification of risks and benefits**, and **selection of participants**.

Procedures for Negotiating the IRB Process

The first thing you will want to do in initiating the IRB process is to obtain IRB guidelines from your university. This is usually easily accomplished. I recommend doing so by contacting the chairperson of your IRB, even volunteering to go over to his or her office to pick them up so that you can review them together and ask any questions you have right at that time. If your school's IRB chairperson is a member of the university's professional staff, you can be sure that the chair will do his or her best to take the time to meet with you. At many places the IRB chair is a faculty member who may be juggling the usual teaching, research and service activities, but at other places the chairperson is staff, not faculty. I'm a faculty member myself, so this is not something I easily admit, but at the universities I've observed it can be a little harder to reach IRB chairs who are faculty, especially during summers. At SUNY Brockport our IRB chair is, as I've mentioned, a member of our professional staff. It's her job to answer IRB concerns and she is always willing to take calls, meet with you (especially if you have to go before the entire board to present your proposal), and she also will read rough drafts of the research proposal and give you feedback. Let me emphasize my point emphatically, thus: don't be afraid to ask for help and consultation. Don't allow self-perceptions of your own naivete' as a researcher, or your lack of experience hold you back. Get into the IRB process and work with them as a colleague and an equal.

The components of the written summary you will have to submit share commonalities at all universities. The minimum elements required in the proposal will include a 1) description, 2) the informed consent form you plan to give to participants, and 3) a copy of each measure, survey, or interview that you will be using. The first part, the "project description", should be

brief but should contain a description of objectives of the study, the planned methods, and the procedure for accomplishing data collection. Descriptions of statistical manipulation of the data post-collection is not necessary as an IRB's charge is only to examine procedures before and during data collection to ensure that participants' welfare is being safeguarded. If you are going to be collecting data in a school setting, you will need a letter of support from the principal or district superintendant before the IRB can grant final approval.

Once your proposal is ready, you will need to obtain signatures on it from the faculty member who is supervising your project, as well as that of the department chairperson, and then forward all the materials to the IRB. The IRB chairperson will make an initial decision as to whether your project is a "risk" or "no-risk" project, and following that assessment, one of three things can occur with your proposal based on three levels of possible "risk".

The first possible outcome is that your project will be deemed a Category I project. This is usually the case for anonymous, mailed surveys on innocuous topics, or anonymous, noninteractive observation of public behavior (e.g. shoppers at a mall). Alternatively, your project could be viewed a Category II proposal, which is usually the decision for studies involving interviews or self-report measures or any data collected either one-on-one or in groups where there is no psychological intervention or deception. In this case, several IRB members will review and evaluate the project's acceptability, and the approval will be conveyed to you via a memo from the chairperson giving you permission to begin. The third possible level of risk is Category III, which is usually applied to studies involving sensitive topics (e.g. sexuality, drug use); or experiments involving deception; or use of "special" populations such as minors. If your project is considered a Catgory III, approval will require a meeting of all of the members

of the IRB before approval can be granted. Usually, the investigator(s) (that include you, as the student researchers) are given the option of being there for the meeting of the IRB so that they can answer any questions. If you are invited, I highly recommend that you go, and take your faculty supervisor with you.

The most common questions or requests for clarifications that an IRB will ask deal with the informed consent form. For example, IRB members may ask for more detail in the informed consent. The informed consent should minimally include statements about the nature of the research, any possible risks, and precautions that the investigator(s) will take against any negative aftereffects. IRB members will also confirm that the informed consent form clearly states that confidentiality of the participants' identity is guaranteed, if participation is not anonymous. Another issue that is vital in judging appropriateness of an informed consent form is its potential for conveying a true level of voluntary consent from participants. Is the form phrased in the potential participants' everyday language, versus being "peppered" with psychological jargon that could confuse someone into volunteering when he or she is not really interested? Is there no coercion in participant recruitment, even of a very subtle or unintentional nature? This is no small matter. The two most common forms of recompense offered participants in psychology experiments are extra course credit; and cash. In the former example, it is extremely common (most of us went through it) to be recruited for participation in psychology experiments while enrolled in large, freshman classes. For these students, even one point of "extra credit" may be very appealing, regardless of what kind of experimental participation is required to obtain it. Similarly, medical schools often receive grants that include money for "subject payments". The participants these investigators then recruit could also be undergraduate students for whom a

typical "honorarium" of $300 for full participation may seem like a fortune. Another issue that may raise IRB questions is use of deception in an experiment. If your project uses any kind of deception, you must have a "debriefing" statement prepared that you will share with your participants, explaining what the deception was and clarifying any mistaken impressions the person may have gotten from not knowing this from the start. Finally, if the research is not anonymous, and the participants will have to give their names, you will have to enumerate your plan for protecting their identities (which can usually be accomplished by use of code numbers and storing consent forms and data separately).

You should receive some feedback from IRB members immediately during the IRB meeting to know how soon they feel they can approve your research plan. Often, it's that same day--the IRB chairperson will give you a written approval statement--and then you are free to begin to conduct your research.

Cautions to Note in Seeking IRB Approval

The first warning I feel I should mention--not to sound too mundane about it or as if I am nagging--is that you must not expect "same day turnaround" on a proposal you submit. Most IRB members are professors, and they are sympathetic to deadlines; to needing to get one's data collected before the end of the term; and other similar pressures. Nonetheless, they will still need to have 3-5 working days to read your proposal and/or schedule a meeting. Therefore, it's best not to wait until the last three weeks of classes to begin semester projects that require IRB review. A second caution is that it's easy, when one is just beginning as a researcher, to desire as much data as possible. You may want to measure as many facets and nuances of behavior as you can possibly think of. From a scholarly standpoint, that's beautiful! However, the view

of the IRB will be that you need to include in your study only those variables that clearly relate to the primary research question, and they may have to disallow data that are not really germane to the reseach question.

Advantages of Learning the IRB Process

Going through the process of having one's research proposal IRB-approved is something that students rarely encounter prior to beginning a master's thesis in graduate school, yet becoming familiar with the procedures as an undergraduate carries with it many advantages. Formally submitting an IRB proposal, signed by one's faculty supervisor and department chair, helps identify the student as the primary investigator on the research and thus "formalizes" his or her ownership of the proposed project. IRB contact familiarizes students with federal guidelines for the protection of participants, a vital skill when they obtain faculty positions and undertake grant funding and major research projects of their own. Finally, you will enhance your skills as a researcher of "good science". IRB members, almost always, love the role of mentor and enjoy guiding and helping.

The IRB process, far from being obstructionistic, can be an informative and enriching part of your research training. May you enjoy your contacts with the IRB, and good luck.

References

Jones, J.H. (1993). Bad blood: The Tuskegee syphilis experiment. New York: Free Press.

Patients' names revealed. (1993, November 16). The Rochester, New York Democrat & Chronicle, pp. 1A, 6A.

Milgram, S.L. (1974). Obedience to authority: An experimental view. New York: Harper & Row.

Rosnow, R.L., Rotheram-Borus, M.J., Ceci, S.J., Blanck, P.D., & Koocher, G.P. (1993). The institutional review board as a mirror of scientific and ethical standards. American Psychologist, 48, 821-826.

Institutional Review Boards and University Student Research: Learning Opportunities

ABSTRACT

Guidelines for research in academic settings are issued by the Office for Protection from Research Risk (OPRR), a division of DHHS, and implemented and enforced by university Institutional Review Boards (IRBs). Negotiating the process of IRB approval may be viewed negatively by college faculty and students, who may perceive the process as obstructionistic or counter to research goals. It need not be, however, and the importance of students' learning IRB procedures (as these relate to psychological research) is increasingly recognized. Experiencing the process of having one's research proposal IRB-approved is something that students rarely encounter prior to beginning a master's thesis in graduate school, yet becoming familiar with the procedures as an undergraduate carries with it many benefits. This paper outlines the process of getting one's research proposal approved by an IRB, including mentioning typical sections involved in an "IRB proposal" for undergraduate or graduate student research; describing an IRB's role in evaluating a proposed research project as ethical and scientific; and articulating advantages of students' learning about IRBs early in their scientific career. Also included are warnings to the beginning researcher of steps to avoid when proposing research that may involve deception, remuneration of subjects, or sensitive topics.

ED 368 042